IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Natasha Smith, individually and on behalf of all others similarly situated, Plaintiff, v. NUTRACEUTICAL WELLNESS, INC., Defendant.	Civil Action No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Natasha Smith ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Nutraceutical Wellness, Inc. ("Defendant"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based on her personal knowledge.

NATURE OF THE ACTION

1. Defendant formulates, manufactures, advertises, and sells its "Nutrafol" hair growth products (the "Products")[1] throughout the United States, including in New York. Defendant markets its Products in a systematically misleading manner by misrepresenting that they are legally sold as "Dietary Supplements" and claiming that the Products are "clinically proven" to improve "hair growth" and prevent "shedding. Defendant's Products are depicted below:

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[1] The Products include Defendants "Nutrafol Women"; "Nutrafol Women's Vegan"; "Nutrafol Women's Balance"; "Nutrafol Postpartum"; and "Nutrafol Men."

2. Because Defendant's sales are driven by consumers seeking products to help restore their hair, Defendant prominently makes these representations, among others, to induce consumers to purchase the Products by representing that they are "clinically proven" to improve "hair growth" and prevent "shedding."

3. Unbeknownst to consumers, however, Defendant' Products are not, in fact,

"clinically proven"—as evidenced by the deeply flawed studies that Defendant relied on in making those statements. To make matters worse, Defendant labels its Products as "hair growth" products which makes them unapproved drugs, and otherwise makes improper disease claims without mandated disclaimers next to its marketing statements in violation of the Food and Drug Administration ("FDA") regulations. As such, the Products are considered unapproved and misbranded "new drugs" under the Food, Drug, and Cosmetic Act ("FDCA") which are illegal to sell and worthless.

4. As a result of its deceptive conduct, Defendant is, and continues to be, unjustly enriched at the expense of its customers.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(a) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of $5,000,000.00 exclusive of interest and costs, there are over 100 members of the putative class, and at least one class member is a citizen of a state different than Defendant.

6. This Court has personal jurisdiction over Defendant because Defendant maintains its principal place of business in New York. Furthermore, a substantial portion of the events giving rise to Plaintiff's claims occurred in New York, including Plaintiff's purchase of the Products.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(1) because Defendant resides in this District.

PARTIES

8. Plaintiff Natasha Smith is a citizen of New York, residing in Queens, New York.

Plaintiff purchased Defendant' Products for her personal use on various occasions within the applicable statute of limitations, with her most recent purchases taking place on February 2, 2023. Plaintiff Smith made these purchases from Defendant's listing posted on www.amazon.com (the "Website") while residing in Queens, New York. Prior to making her purchases, Plaintiff Smith saw that the Products were labeled and marketed for "Hair Growth" as well as other statements that Defendant wrote on the Website claiming that the Products were "clinically proven" to improve "hair growth" and prevent "shedding." Plaintiff Smith also saw that the Website claimed that the Products were "Physician-formulated to improve hair growth from within by targeting the 6 root causes of thinning hair in women–including stress, hormones, and aging." Plaintiff Smith relied on Defendant' representations when she decided to purchase the Products. Plaintiff saw those representations prior to and at the time of her purchases and understood them as a representation and warranty that the Products were "clinically" effective in improving "hair growth" and that the Products "prevent shedding". Plaintiff Smith relied on these representations and warranties in deciding to purchase the Products. Accordingly, those representations and warranties were part of the basis of her bargains, in that she would not have purchased the Products on the same terms had she known that those representations were not true. Furthermore, in making her purchases, Plaintiff Smith paid a substantial price premium due to Defendant's false and misleading claims regarding the Products' "clinically proven" ability to improve "hair growth" and prevent "shedding." Plaintiff Smith, however, did not receive the benefit of her bargains because the Products were not, in fact, "clinically proven" to achieve those results. In fact, Plaintiff Smith did not experience any meaningful hair growth or prevention of shedding despite using the Products for almost a year. Had Plaintiff Smith known that Defendant's representations and warranties were false, she would not have purchased the

Products or paid substantially less for them.

9. In addition, in making her purchases, Plaintiff Smith did not see any disclaimer that the Products' claims and representations had not been "evaluated by the Food and Drug Administration" or that the Products were "not intended to diagnose, treat, cure, or prevent any diseases." Those omissions were material to Plaintiff Smith because had she known that Defendant's representations and warranties were qualified by those disclaimers, she would not have relied on them or believed that the Products were equally efficacious to other FDA "clinically proven" products on the market. As such, Plaintiff Smith would not have purchased the Products or would have paid substantially less for them had she seen the FDA required disclosures on the Products' labeling and marketing.

10. Finally, had Plaintiff known that Defendant's Products were adulterated, misbranded, and illegal to sell under the FDCA, she would not have purchased them at all.

11. Defendant Nutraceutical Wellness, Inc., is a Delaware corporation with its principal place of business in New York, New York. Defendant manufactures, markets, and sells the Products throughout New York and the United States.

GENERAL ALLEGATIONS

Overview of Defendant's Hair Growth Business

12. Hair loss is a medical condition that affects millions of people in the United States. According to the American Hair Loss Association, approximately 64% of men begin to experience hair thinning by the age of 35, and 40% of women begin to experience hair thinning by the age of 40.[2]

[2] https://www.americanhairloss.org (last accessed May 4, 2023).

13. American consumers are spending more and more on hair repair products every year. Although there are only three FDA-approved drugs that are clinically proven to help treat hair loss,[3] there is an increase in the number of individuals using hair growth supplements and/or cosmetics.

14. The market for hair growth supplements is expected to exceed $2.86 billion dollars by 2031, with the US holding the largest share of 33%.[4] This demand for hair growth supplements has skyrocketed as "[e]xcessive hair fall has become one of the most serious health concerns among people affected with COVID-19."[5]

15. Defendant is among the major players that have capitalized on this demand. "Since March 2020, Nutrafol experienced an 80% jump in new customer sales, as there was an increase in anecdotal reports of people experiencing stress-induced hair loss due to Covid-19 and quarantine."[6] According to industry sources, Defendant's revenue in 2021 approximated $150 to $175 million dollars.[7] On July 7, 2022, Unilever, one of the largest multinational food and cosmetics companies in the world, acquired 67% of the shares of Defendant for $800 million euros, bringing its total investment in the company to 80%.[8]

Defendant's Products are Unapproved "New Drugs" under the FDCA

16. The FDCA defines a "drug" as any article "intended for use in the diagnosis, cure,

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[3] https://www.americanhairloss.org/men_hair_loss/treatment.html (last accessed May 4, 2023). *See also* footnote 17, *infra*.

[4] https://www.transparencymarketresearch.com/hair-supplements-market.html (last accessed May 4, 2023).

[5] *Id.*

[6] https://www.glossy.co/beauty/nutrafol-looks-to-reach-150-million-in-2021-top-line-revenue/ (last accessed May 4, 2023).

[7] *Id.*

[8] Unilever PLC, Form 6-k Report of Foreign Issuer (February 9, 2023), https://www.sec.gov/Archives/edgar/data/217410/000165495423001506/a4291p.htm

mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1). The FDCA and its implementing regulations are explicit that "dietary supplements '***intended*** for use in diagnosis, cure, mitigation, treatment, or prevention of disease' remain within the definition of a 'drug.'" 65 Fed. Reg. at 1001; *see also* 21 U.S.C. § 321(g)(1)(B). Pursuant to FDA regulations, the "intended use" of an article is determined based on the "objective intent of the person legally responsible for the labeling of the drug," and may be determined for example, "by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128. The FDCA defines "label" as, among other things, "a display of written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k); and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

17. Here, Defendant's Products are "drugs" rather than dietary supplements for the simple reason that their front labels conspicuously state that their intended use is to improve "hair growth." FDA regulations expressly establish that hair growth products are "new drugs." 21 C.F.R. § 310.527(b) ("Any OTC drug product that is labeled, represented, or promoted for external use as a hair grower or for hair loss prevention is regarded as a new drug [under the FDCA] for which an approved new drug application…is required."). Defendant has not filed an application with the FDA for approval of its Products, although they are qualified as "new drugs." As a result of the "absence of an approved new drug application," Defendant's Products are "also misbranded under the [FDCA]." *Id.*

18. Indeed, the FDA has repeatedly admonished companies who labeled and/or advertised their dietary supplements and cosmetic products for hair growth or hair loss prevention, like Defendant's Products, as unapproved drugs that are not generally recognized as

safe and effective for the uses and claims made by Defendant.[9]

19. Finally, Defendant's extensive marketing and disease claims, discussed in greater depth below, demonstrate Defendant's intent to sell the Products as drugs rather than dietary supplements. In fact, the Products' labels indicate that they are made with "medical-grade ingredients." *See infra* ¶ 35.

Defendant's Products Make Disease Claims in Violation of the FDCA

20. Assuming that Defendant's Products do not qualify as "new drugs"—despite the

[9] *See, e.g.*, ***FDA warning letter to Santhigram Kerala Ayurvedic Co. of U.S., Inc.***, (May 19, 2022) ("Examples of claims observed on your website and social media websites that establish the intended use of your Santhigram ayurvedic products as drugs included, but are not limited to, the following: … 'Benefits: Triphala has several health benefits, such as; … stimulates hair growth…'"), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/santhigram-kerala-ayurvedic-co-us-inc-625892-05192022 ; ***FDA warning letter to Speedwinds Nutrition, Inc.***, (Dec. 22, 2020) ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include the following: …'With Sephren, you can feel confident that Sephren will: . . . Stop the root causes of hair [sic] female hair loss.'"), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/speedwinds-nutrition-inc-609298-12222020 ***; FDA warning letter to Star Health & Beauty LLC***, (May 26, 2017), ("Examples of some of the claims that provide evidence that your products are intended for use as drugs include: … 'HGH has been found to reverse and/or slow down the aging process by: … Restoring lost hair growth' … 'Fuller Thicker Hair In As Little As Two Months,' '[A] natural alternative to combat hair loss…,' 'Restore thinning hair with visible results,' '[R]estores and maintains healthy hair.,'… '[T]o restore thickness and prevent more hair from falling out.,' 'Nugen HP – The All-Natural Hair Restoration System?,' '[R]evitalizes your hair follicles stimulating fuller, thicker hair.'"), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017; ***FDA warning letter to Soleo*** (Dec. 13, 2018) ("Unapproved New Drugs 'GEN+LE THERAPY Shampoo' Examples of claims … that establish the intended uses of the product as defined in 21 CFR 201.128 include, but may not be limited to, the following: … 'Prevents Hair Loss…Hair Loss Prevention…' … Based on the above claims, 'GEN+LE THERAPY Shampoo' is a 'drug' as defined by section 201(g)(1)(B) of the FD&C Act (21 U.S.C. 321(g)(1)(B)) because it is intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act (21 U.S.C. 321(g)(1)(C)) because it is intended to affect the structure or any function of the body. Specifically, this product is intended as a hair growth, hair loss prevention, and anti-dandruff drug product."), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/soleo-567046-12132018

FDA's abundant warning letters and its clear intention under 21 C.F.R. § 310.527(b) that they do—the Products nonetheless make improper "disease" claims in contravention to the FDA's regulations governing dietary supplements. A dietary supplement is a product that is "intended to supplement the diet" and "contains one or more [] dietary ingredients." 21 U.S.C. § 321(ff). Under the FDCA, dietary supplements can make "structure or function" claims but not "disease claims." 21 U.S.C. § 343(r)(6). A structure/function is a statement that, *inter alia*, "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, which characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A).

21. Manufacturers of dietary supplements are prohibited from making any statement that "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly. 21 C.F.R. § 101.93(g). The FDA defines "disease" as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition." *Id.* Generally, a statement is a disease claim if it states explicitly or implicitly that the product:

(a) has an effect on a disease, a characteristic sign or symptom of a disease, or an abnormal condition that is either uncommon or can cause significant harm;

(b) has an effect on a disease by implication through, for example, the product name, an ingredient in the product, citation to literature referencing a disease or other product label details implying connection to a disease;

(c) is a substitute for, is similar to, or augments a product that does diagnose, treat, or prevent a disease;

(d) has a role in the body's response to a disease; or e treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events themselves constitute diseases.

21 C.F.R. § 101.93(g)(2).

22. Applying these criteria to Defendant, the Products go beyond structure/function claims by making statements related to the causes, symptoms, and treatment of a group of diseases: namely, alopecia areata and telogen effluvium (among others). Alopecia areata is an autoimmune disease that causes the immune system to attack healthy hair follicles, leading to hair loss.[10] The FDA has paid special attention to alopecia areata when it held a focus group on the topic—hearing from patients and doctors alike. According to the FDA:

> "Alopecia areata is an autoimmune disease which targets the hair follicles, causing hair loss. The hair loss usually occurs on the scalp, but can also affect the beard, eyebrows, and other areas of the body. In the United States, approximately 500,000 individuals have alopecia areata."[11]

23. Although the exact causes of alopecia areata are still being researched, there is a scientific consensus that the disease can be triggered by environmental factors—including

[10] https://www.health.harvard.edu/blog/what-is-alopecia-areata-and-how-is-it-managed-202204282732 (last accessed May 5, 2023).
[11] FDA, The Voice of the Patient Alopecia Areata (March 2018), https://www.fda.gov/files/about%20fda/published/Alopecia-Areata--The-Voice-of-the-Patient.pdf (last accessed May 4, 2023).

emotional distress arising from stressful life events,[12] heavy metals contained in diets,[13] hormonal imbalances resulting from childbirth,[14] and menopause.[15] On June 13, 2022, the FDA approved the first oral tablets for the treatment of alopecia areata under the brand Olumiant "(baricitinib).[16]

24. Telogen effluvium is an abnormal condition that disrupts the normal balance of hair follicles by causing a large number of hair follicles to enter their resting phases (telogen) prematurely, leading to a temporary cessation of hair growth and subsequent hair loss. Telogen effluvium shares many of the core roots as alopecia areata—including acute psychological stress, dietary irregularities (*e.g.*, consumption of heavy metals), childbirth, and postpartum.[17] Physicians regularly prescribe minoxidil (Rogaine) to help patients combat telogen effluvium.[18] Defendant makes disease claims in violation of the FDA by citing physicians on its website who recommend the Products' use as a substitute for minoxidil and other clinical therapies in treating telogen effluvium:

> "Telogen effluvium can become chronic and we encourage supportive care for the scalp. Some in-office therapies include red light treatments and PRP (platelet rich

[12]Sellami, R., Féki, I., Masmoudi, R., Hentati, S., Turki, H. and Masmoudi, J., 2020. *Stressful life events in alopecia areata patients: A case control study*. Our Dermatol Online, 11., https://pdfs.semanticscholar.org/d836/c943d481a6f383e104571c081f6fc14eb51d.pdf
[13] Paolo Daniele Pigatto, Silvia Mariel Ferrucci, Lucia Brambilla, Gianpaolo Guzzi; *Alopecia Areata and Toxic Metals.* Skin Appendage Disord 15 June 2020; 6 (3): 177–179.
[14] Cho SI, Yu DA, Kim SI, Lee SM, Kwon O. *Pregnancy Outcomes in Female Patients with Alopecia Areata: A Nationwide Population-Based Study.* J Invest Dermatol. 2021 Jul; https://www.jidonline.org/article/S0022-202X(20)32412-X/fulltext
[15] Grymowicz, M.; Rudnicka, E.; Podfigurna, A.; Napierala, P.; Smolarczyk, R.; Smolarczyk, K.; Meczekalski, B. *Hormonal Effects on Hair Follicles.* Int. J. Mol. Sci. 2020, 21, 5342, https://www.mdpi.com/1422-0067/21/15/5342
[16] FDA, *FDA Approves First Systemic Treatment for Alopecia Areata* (June 13, 2022), https://www.fda.gov/news-events/press-announcements/fda-approves-first-systemic-treatment-alopecia-areata (last accessed May 4, 2023)
[17] https://www.ncbi.nlm.nih.gov/books/NBK430848/ (last accessed May 4, 2023)
[18] https://www.drugs.com/health-guide/telogen-effluvium.html (last accessed (May 4, 2023).

> plasma) injections. Other home therapies include a restorative hair vitamin **such as Nutrafol**, proper diet and self-care, management of stress, and, [if the problem] is ongoing, over-the-counter **Minoxidil**."[19] (emphasis added)

25. In yet another article, Defendant claims that a number of the ingredients in the Products can help combat alopecia areata:

> "Current treatment options [for alopecia areata] include topical steroids, as well as injectable steroid applied directly on the patches. Immune system suppressants have also been used topically. On the natural side, ingredients that can help support your immune system and improve the body's resilience to stress include **ashwagandha, zinc, selenium, B complex vitamins, vitamin D, antioxidants, and vitamin A.**" [20] (emphasis added)

26. These citations imply that the Products have an effect on alopecia areata and telogen effluvium by comparing or contrasting the Products with other products or interventions that do diagnose, treat, or prevent these diseases. Defendant's citations also imply that the Products could be used to substitute or augment existing therapies used to treat these diseases. In so doing, Defendant has made improper disease claims in violation of 21 C.F.R. § 101.93(g)(2).

27. Defendant's disease claims, however, do not stop there. Throughout its website, Product labels, and marketing materials, Defendant makes a myriad of other hair-related diseases. For example, on its Amazon listings, Defendant states that the Products are "***clinically effective*** and "***[p]hysician-formulated*** to improve hair growth from within by targeting the ***6 root causes of thinning hair in women–including stress, hormones, and aging***."[21] (emphasis

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[19] https://nutrafol.com/blog/telogen-effluvium-symptoms-and-treatment/ (last accessed May 4, 2023).
[20] https://nutrafol.com/blog/the-4-different-types-of-hair-loss-what-can-help/ (last accessed May 4, 2023).
[21] https://www.amazon.com/Nutrafol-Growth-Thicker-Stronger-

added). Defendant elaboration of these "6 root causes" on its website contains a myriad of disease claims in violation of 21 C.F.R. § 101.93(g)(2), as depicted by the images and text in the chart below:

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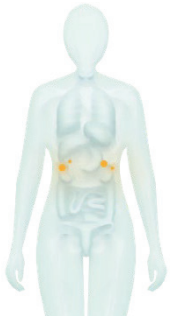
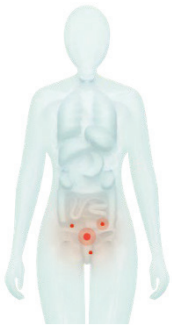
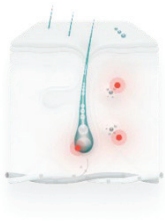
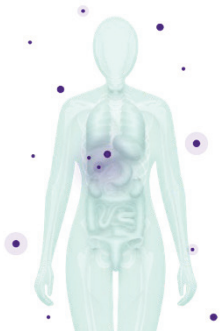
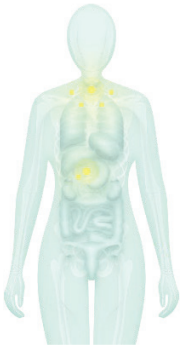
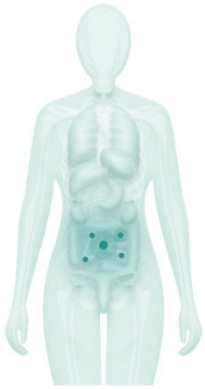
Capsules/dp/B00LU4CZP8/ref=sr_1_6?crid=1CD3ASW586JDG&keywords=nutrafol&qid=1682538632&sprefix=nutrafol%2Caps%2C260&sr=8-6 (last accessed April 26, 2023).

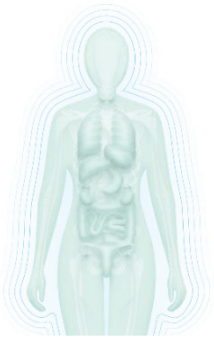
Defendant's Statements and Sources	Images Depicting Damaged Organs	Disease Claims Conveyed
Stress 1. **"Signs of stress"** "Shedding or thinning hair, not just at the hairline or part. You also may feel like you have trouble sleeping or waking up, or feel tired or wired throughout the day." 2. **"How it affects your hair"** "The stress hormone cortisol [which] signals hair follicles to prematurely shift out of the hair growth phase, accelerating the time it takes for hair to shed. Over time, stress can also disrupt hormone and nutrient absorption needed for hair growth." 3. **"How we target it"** Ashwagandha 10% withanolides is one way Nutrafol's Hair Growth Nutraceuticals addresses stress. Ashwagandha is an adaptogen that helps balance stress hormones in the body." https://nutrafol.com/science (last accessed May 3, 2023). https://nutrafol.com/de-stress-hair-growth-duo/ (last accessed May 3, 2023).	**In the Body**  **At the Follicle** 	1. Conveys the message that hair loss is symptomatic of the following diseases: insomnia and generalized anxiety disorder. 2. Conveys the message that stress leads to hair loss by causing abnormal conditions relating to "hair growth phases" as well as pathological hormonal and nutritional imbalances. 3. Conveys the message that the Products can help prevent, mitigate, treat, or cure hair loss by restoring the imbalance caused by stress hormones.

Defendant's Statements and Sources	Images Depicting Damaged Organs	Disease Claims Conveyed
Hormones 1. **"Signs of hormonal effects"** "Hormones biologically affect hair growth in men and women differently. Men may show changes at the hairline and overall thinning, while women often see part line changes. Women may also experience unwanted facial hair growth, and irregular periods due to perimenopause." 2. **"How it affects your hair"** "Changes in hormones can make your body more susceptible to DHT hormone. DHT hormone causes hair follicles to shrink (miniaturize) and eventually close completely so hair can no longer grow." 3. **"How we target it"** "Saw Palmetto is one way Nutrafol's Hair Growth Nutraceuticals support hormonal impacts on hair. Saw Palmetto helps lower the conversion of testosterone to follicle-shrinking DHT hormone to promote hair growth." https://nutrafol.com/science (last accessed May 3, 2023). https://nutrafol.com/hormone-support-hair-growth-duo/ (last accessed May 3, 2023).	**In the Body**  **At the Follicle** 	1. Conveys the message that hair loss is symptomatic of the following diseases: unexpected facial hair growth and irregular periods due to hormonal androgen imbalances. 2. Conveys the message that DHT hormonal imbalances can lead to a pathological condition which causes "hair follicles to shrink" and eventually "close completely" leading to total hair loss. 3. Conveys the message that the Products can help prevent, mitigate, treat, or cure hair loss, facial hair growth, and missed periods by lowering abnormally high DHT hormones.

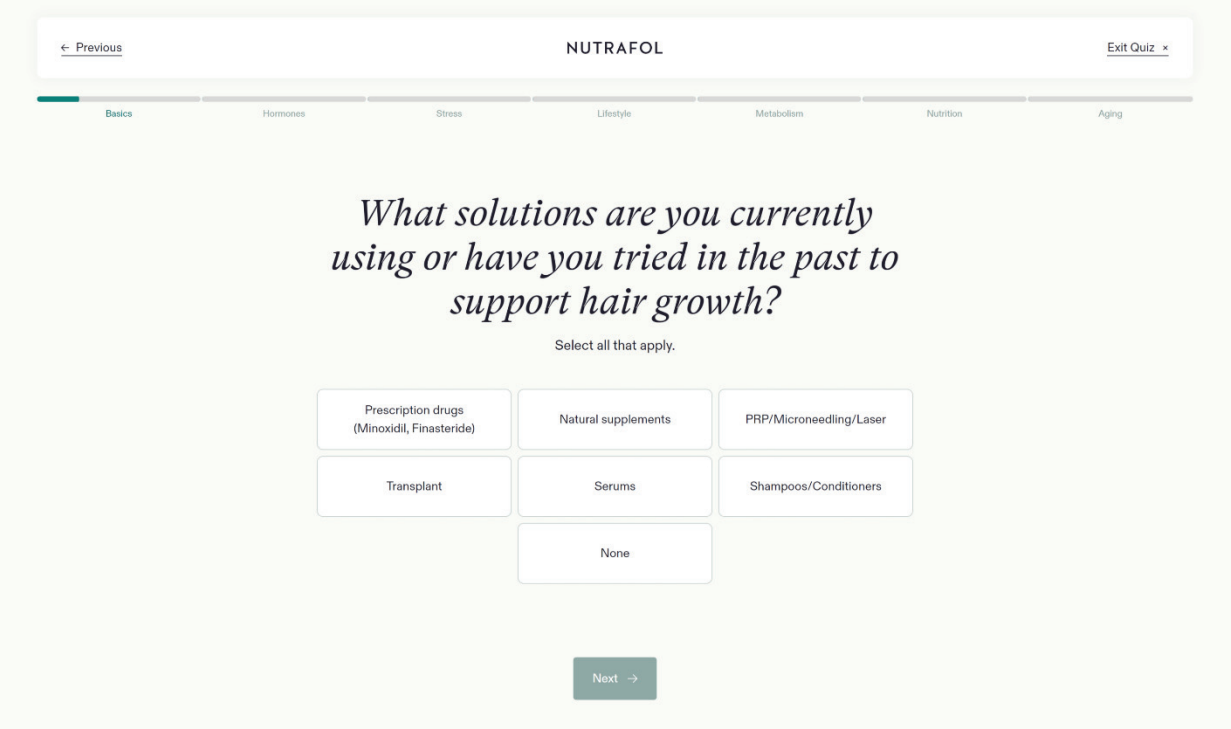
Defendant's Statements and Sources	Images Depicting Damaged Organs	Disease Claims Conveyed
Lifestyle 1. **"Signs of lifestyle effects"** "Damaged hair that is weak, brittle, and breaking." 2. **"How it affects your hair"** "Lifestyle refers to your surroundings, the products you use, and the foods you eat, which can weaken the health of the hair follicle." 3. **"How we target it"** "Tocotrienol Complex, a concentrated form of vitamin E, is one way Nutrafol's Hair Growth Nutraceuticals provides antioxidant support against environmental stress to improve hair density." https://nutrafol.com/science (last accessed May 3, 2023). https://nutrafol.com/toxin-cleanse-hair-growth-duo/ (last accessed May 3, 2023).	**In the Body**  **At the Follicle** 	1. Conveys the message that a person's lifestyle can lead to "damaged' hair which might result in permanent damage to the thickness and overall health of a person's hair and/or hair loss. 2. Conveys the message that certain lifestyle choices, including the products and food that a person consumes, can lead to the abnormal "health" condition (*i.e.*, disease) of damaging their "hair follicle[s]" 3. Conveys the message that the Products can help prevent, mitigate, treat, or cure abnormal "health" conditions leading to "damaged" hair by acting as an "antioxidant" which protects people's hair from dangerous products and foods, and combats the damage already incurred by the consumption of such products and foods.

Defendant's Statements and Sources	Images Depicting Damaged Organs	Disease Claims Conveyed
Metabolism 1. **Intro** "Over 100 million Americans are living with blood sugar issues." 2. **"Signs metabolism is playing a role"** "Breakage and hair that is having trouble growing can be a sign of metabolism on hair. You can often see this through age or difficulty managing your weight." 3. **"How it affects your hair"** "Your cellular metabolism receives nutrients and signals from the body to provide energy for your hair." 4. **"How we target it"** "Curcumin, standardized with 45% curcuminoids, is one way Nutrafol's Hair Growth Nutraceuticals support metabolism. It is a robust antioxidant that supports metabolic function and multiple root causes of hair thinning." https://nutrafol.com/science (last accessed May 3, 2023). https://nutrafol.com/energy-hair-growth-duo/ (last accessed May 3, 2023).	**In the Body**  **At the Follicle** 	1. Conveys the message that people might be experiencing hair loss due to diabetes (*i.e.*, a disease) 2. Conveys the message that a person's metabolism can lead to "breakage" and hair that has "trouble growing" due to abnormal metabolic conditions including those which lead to obesity. 3. Conveys the message that metabolic conditions can lead to the depletion of the nutrients required for hair growth at a cellular level. 4. Conveys the message that the Products can help prevent, mitigate, treat, or cure abnormal "metabolic" conditions (*e.g.*, diabities and weight loss complications) leading to "breakage" and imparied hair growth by introducing an "antioxidant" which helps restore abnormal metabolic imbalances that combats multiple causes of "hair thinning."

Defendant's Statements and Sources	Images Depicting Damaged Organs	Disease Claims Conveyed
Nutrition 1. **"Signs of inadequate nutrition"** "Brittle, dry hair or all over thinning can be signs of gaps in the body's nutrients that are needed to support healthy hair growth. You may also notice bloating or digestive complaints." 2. **"How it affects your hair"** "Key nutrients are needed to build hair and support a healthy hair growth cycle. As a micro-organ, our hair follicle is affected by nutrient deficiencies. This can be further impacted by stress or nutrient absorption from the gut microbiome." 3. **"How we target it"** "Marine Collagen Peptides, vitamins and minerals are some ways Nutrafol Hair Growth Nutraceuticals help provide the building blocks of strong hair fibers." https://nutrafol.com/science (last accessed May 3, 2023). https://nutrafol.com/gut-microbiome-hair-growth-duo/ (last accessed May 3, 2023).	**In the Body**  **At the Follicle** 	1. Conveys the message that a person's "brittle" and "all over thinning" hair might be symptomatic of abnormal nutritional deficiencies associated with abnormal gastrointestinal conditions or diseases (*i.e.*, "bloating or digestive complaints"). 2. Conveys the message that nutritional deficiencies can affect the "micro-organ" of "hair follicle[s]" which is closely associated with excessive stress and/or other abnormal conditions that can affect the normal functioning of the "gut microbiome." 3. Conveys the message that the Products can help prevent, mitigate, treat, or cure abnormal nutritional deficiencies that lead to abnormal levels of "hair thinning" arising from abnormal conditions that impact the body's ability to produce hair, such as high levels of stress and/or other gastrointestinal medical complications.

Defendant's Statements and Sources	Images Depicting Damaged Organs	Disease Claims Conveyed
Aging 1. **"Signs of aging"** "Hair thinning, coarse texture, weakened hair that grows slowly, thin skin, fine lines and wrinkles, achy joints, and brittle bones can all be signs of aging." 2. **"How it affects your hair"** "The scalp loses collagen and elastin as you age. This structural breakdown prevents key components like blood vessels, lipids, melanocytes, and nerve endings from protecting, hydrating, and replenishing nutrients needed for hair growth. As a result, hair becomes shorter, weaker, and less pigmented." 3. **"How we target it"** "We use Marine Collagen Peptides to replenish key amino acids that build strong hair and provide hydration to the scalp, plus Vitamin D to reduce hair damage." https://nutrafol.com/science (last accessed May 3, 2023). https://nutrafol.com/strengthening-hair-growth-duo/ (last accessed May 3, 2023).	**In the Body**  **At the Follicle** 	1. Conveys the message that a person's "hair thinning" and "weakened hair" might be symptomatic of diseases that come with aging including "achy joints" (*i.e.*, arthritis)," thin skin" (*i.e.*, dermatoporosis) and "brittle bones" (*i.e.*, osteoporosis). 2. Conveys the message that hair loss might be caused by serious medical conditions affecting people's "blood vessels, lipids, melanocytes, and nerve endings." 3. Conveys the message that the Products can help prevent, mitigate, treat, or cure abnormal medical conditions associated with old age which can lead to hair damage by "replenish[ing] key amino acids" that can help combat those underlying medical complications.

28. Defendant even goes as far as providing a detailed questionnaire to consumers on its website[22] to pinpoint the exact causes of their hair loss—implying that its products are a substitute for, are similar to, or augment prescription products that do diagnose, treat, or prevent alopecia areata, telogen effluvium, and other possible diseases that might cause hair loss.[23] For example, Defendant asks consumers what they are "currently using or have [] tried in the past to support hair growth," including: (1) prescription drugs ("minoxidil" and "finasteride"); (2) surgery (hair "transplant"); and (3) medical therapies (platelet-rich plasma injections, "microneedling," and "laser"):



29. At the end of the "quiz," Defendant recommends to consumers the Products

[22] https://nutrafol.com/hair-wellness-quiz-intro/ (last accessed May 4, 2023).
[23] Specifically, Defendant asks consumers whether they have diseases or abnormal conditions that can lead to hair loss, including whether they have: (1) "acne located along the jawline or chin"; (2) "unpredictable periods"; (3) "unwanted facial hair"; (4) "trouble sleeping"; "inflammation"; (5) hormone imbalance"; (6) "thyroid imbalance"; and (7) "a major stressful event (big move, breakup, job change, surgery)." *Id.*

which best serve their needs and personalized solutions based on the medical symptoms and other dietary/environmental factors presented in the questionnaire. Alarmingly, Defendant also includes "1-on-1 consultations with naturopathic **doctors** for growth guidance plus **optional referrals to local MDs**." (emphasis added). Defendant's "quiz" is a textbook example of the diagnosis, treatments, and cures prohibited by the FDA.

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Quiz Results

NUTRAFOL

Exit Quiz ×

Thank you [redacted]
here are your results.

Based on your hair growth goals, your recommended formula is **Women's Balance**. **Nutrition** could also use some extra support from a Hair Wellness Booster to maximize your results.

Learn About Root Causes →

Address all hair growth factors from within.

Targets All Factors

Women's Balance ~~$88~~ **$79/mo**

Container: 120 Capsules
Dosage: 4 Capsules

Improves hair growth with visibly more thickness peri- and postmenopause. Target root causes of thinning like hormones, stress, and metabolism with 100% drug-free, natural ingredients that support your whole-body health.

View Ingredients

✓ Added

Targets Nutrition

Hairbiotic ~~$39~~ **$19/mo**

Container: 30 capsules
Dosage: 1 capsule

Targets the gut microbiome as a root cause of compromised hair nutrition with 11 strains of pre- and probiotics known to help improve hair quality.

View Ingredients

✓ Added

Order Summary

GrowthPlan

Women's Balance	$79/mo
Hairbiotic Remove	$19/mo
Doctors On-Call 1-on-1 consultations with naturopathic doctors for growth guidance plus optional referrals to local MDs.	~~$75~~ Included
Hair Mineral Analysis Measure your progress towards hair wellness with in-depth lab tests every 6 months.	~~$125~~ Included
GrowthPlan Total Billed Monthly	~~$318~~ **$98/mo**

Due Today **$98.00**

Add to Cart →

The Hair Wellness Evaluation is to be utilized for educational purposes only. The Hair Wellness Evaluation is not intended to diagnose or treat any health or medical condition, nor is it intended to take the place of the advice of your qualified healthcare professional. Consultation with a qualified healthcare professional and other methods of testing are required to diagnose a health or medical condition. Never disregard qualified healthcare advice or delay in seeking it because of the results of the Hair Wellness Evaluation . Always seek the advice of a qualified healthcare professional before beginning, modifying or ending any medical treatment. These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

30. Throughout its extensive marketing, as set forth above, Defendant has purposefully made various disease claims[24] in violation of the FDA regulations governing dietary supplements. 21 C.F.R. § 101.93 (g).

Defendant Does Not Provide FDA Mandated DSHEA Disclaimers

31. To make matters worse, all of Defendant's statements about its Products fail to include a mandatory disclaimer stating that they have not been evaluated by the FDA, nor are intended to diagnose, cure, or prevent a disease (the "DSHEA Disclaimer."). 21 U.S.C. §§ 343(f),[25] 343(r)(1)(B), 343(r)(6); 21 C.F.R. § 101.93(d) ("On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there [is a structure/function claim].").

32. The DSHEA Disclaimer must be prominent and bolded, and it must read:

> **These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

21 U.S.C. § 343(r)(6)(C); *see also* 21 C.F.R. § 101.93(c)(2).

33. To be prominent, the disclaimer may not be crowded with voluntary information or imagery and additionally must be in bolded font *at least* 1/16th of an inch in size. 21 C.F.R. § 101.93(e). The disclaimer must appear on all panels with structure/function claims. The Food

[24] Other disease claims made by Defendant through its marketing can be found in the Truth in Advertising's letter to the FTC, which are incorporated here by reference. Truth in Advertising, Inc, *Letter to the Federal Trade Commission Regarding Nutrafol's Widespread Deceptive Marketing Campaign* (April 4, 2023). Exhibit B at pgs. 2-4.

[25] 21 U.S.C. § 343(f) ("If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customer conditions of purchase and use.").

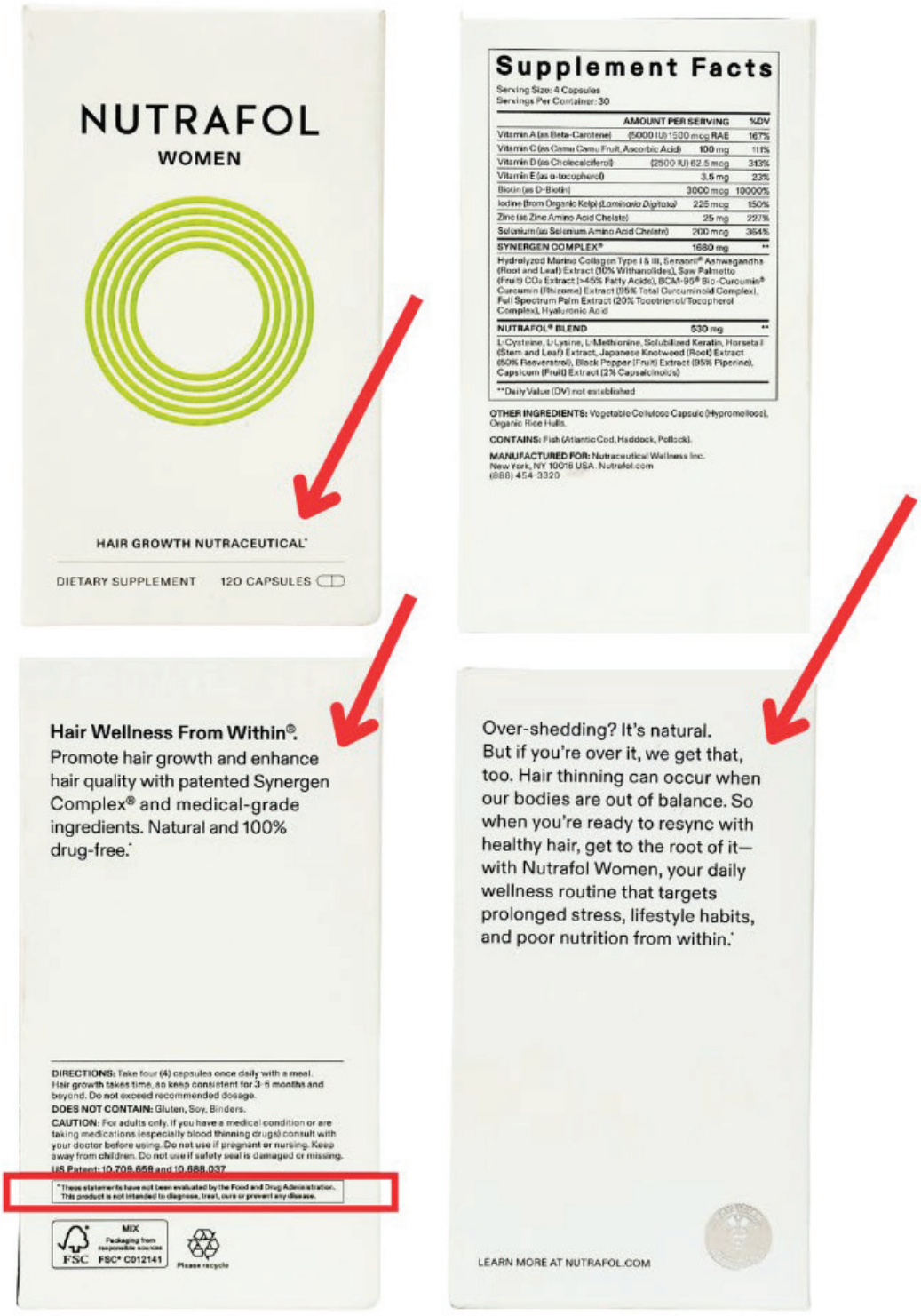
and Drug Administration has specifically rejected the proposition "that repetition of the disclaimer on every panel or page where a statement [is] made…is unnecessary." 62 Fed. Reg. 49,859, 49,864 (Sept. 23, 1997) To meet statutory requirements, "**the disclaimer must be within the same field of vision as the statement itself**." *Id.* at 49865 (emphasis added). *see also id.* at 49,864 ("FDA has evaluated the comments and concludes that the placement of the disclaimer on a panel other than where the statement is made would not meet the statutory requirement for the placement of the disclaimer….Based on its experience with asterisks within the nutrition label, the agency concludes that consumers are accustomed to using asterisks on labels to associate two discrete pieces of important information when they are in the ***same field of vision***.") (emphasis added) (citation omitted).

34. Defendant fails to abide by the disclaimer requirements in labeling and marketing its Products.

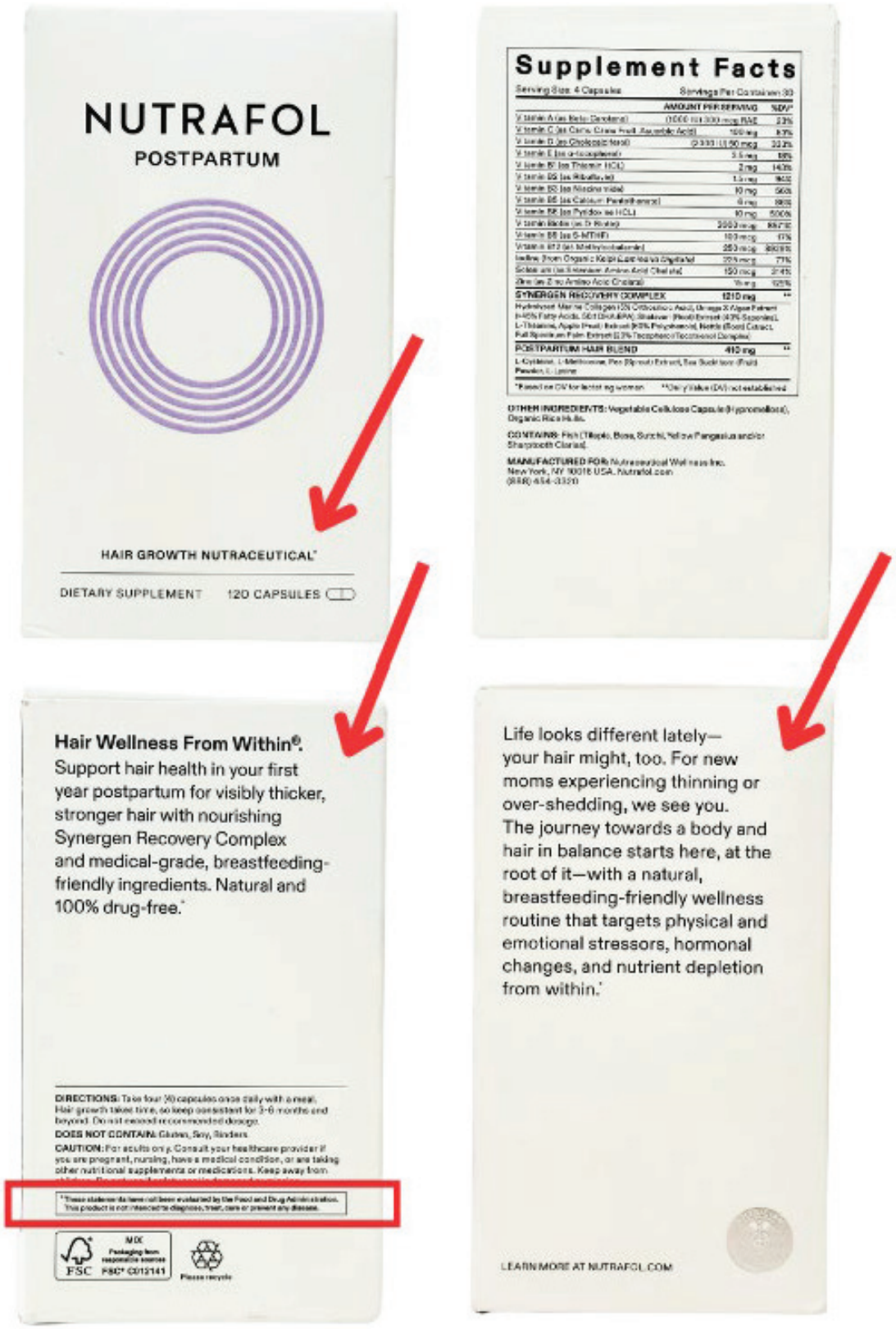
35. First, Defendant omits the DSHEA Disclaimer ***altogether*** from the front and left side panels of the external packaging of all of its Products, despite the presence of claims on both panels.[26] Further, although there is a DSHEA Disclaimer on the right label of the Products, it is not prominently displayed and is otherwise buried in a mass of other unrelated statements at the bottom of the label. In addition, the asterisk accompanying the Products' statements is so tiny that it is invisible to the naked eye. Finally, although the Products themselves have a DSHEA Disclaimer on their back label, these disclaimers are also inconspicuously buried at the very bottom with other unrelated statements; and the asterisks are even less noticeable than the packaging because they are placed next to copyright symbols. Two of Defendant's Products are

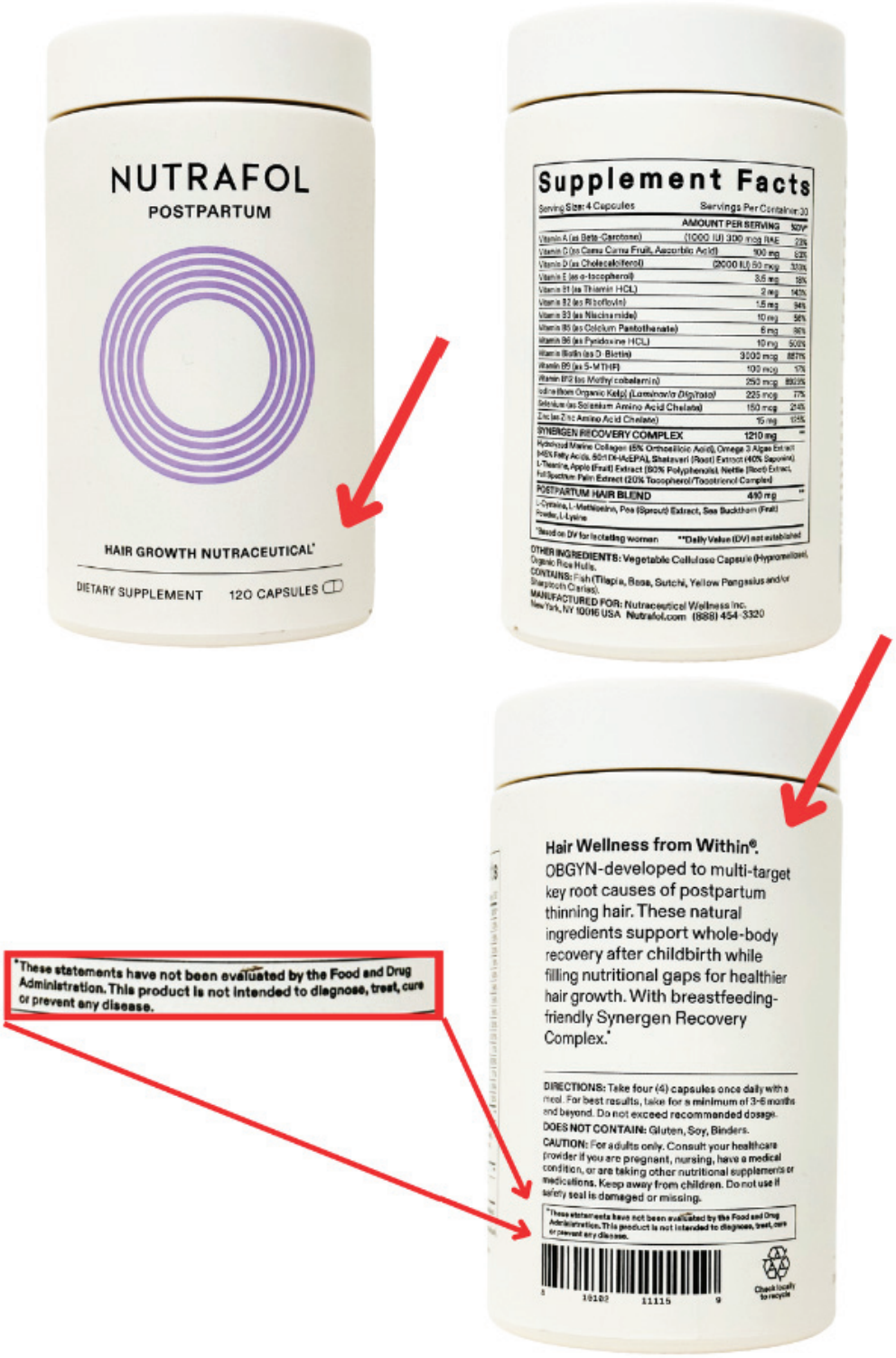
[26] All of the Products are substantially identical in terms of design and the claims made on their panels.

displayed below, by way of illustration (red box and arrows for emphasis):




NUTRAFOL
WOMEN
HAIR GROWTH NUTRACEUTICAL*
DIETARY SUPPLEMENT
120 CAPSULES
Supplement Facts
AMOUNT PER SERVING
SYNERGEN COMPLEX®
1680 mg
NUTRAFOL® BLEND
530 mg
OTHER INGREDIENTS: Vegetable Cellulose Capsule (Hypromellose)
CONTAINS: Fish (Atlantic Cod, Haddock, Pollock).
MANUFACTURED FOR: Nutraceutical Wellness Inc.
Hair Wellness from Within®.
Physician-formulated to multi-target key root causes that compromise hair health. Clinically shown to promote hair growth and improve hair quality in women. 100% drug-free. With stress adaptogens and growth-powering patented Synergen Complex®.*
DIRECTIONS: Take four (4) capsules once daily with a meal. For best results, take for a minimum of 3-6 months and beyond. Do not exceed recommended dosage.
DOES NOT CONTAIN: Gluten, Soy, Binders.
CAUTION: For adults only. If you have a medical condition or are taking medications (especially blood thinning drugs) consult with your doctor before using. Do not use if pregnant or nursing. Keep away from children. Do not use if safety seal is damaged or missing.
US Patent: 10,709,659 and 10,688,037
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.


NUTRAFOL
POSTPARTUM
HAIR GROWTH NUTRACEUTICAL*
DIETARY SUPPLEMENT
120 CAPSULES
Supplement Facts
Serving Size: 4 Capsules
Servings Per Container: 30
AMOUNT PER SERVING
%DV*
SYNERGEN RECOVERY COMPLEX
1210 mg
POSTPARTUM HAIR BLEND
410 mg
OTHER INGREDIENTS: Vegetable Cellulose Capsule (Hypromellose), Organic Rice Hulls.
CONTAINS: Fish (Tilapia, Bass, Sunchi, Yellow Pangasius and/or Sharptooth Clarias).
MANUFACTURED FOR: Nutraceutical Wellness Inc.
New York, NY 10016 USA. Nutrafol.com
(888) 454-3331
Hair Wellness From Within®.
Support hair health in your first year postpartum for visibly thicker, stronger hair with nourishing Synergen Recovery Complex and medical-grade, breastfeeding-friendly ingredients. Natural and 100% drug-free.*
DIRECTIONS: Take four (4) capsules once daily with a meal. Hair growth takes time, so keep consistent for 3-6 months and beyond. Do not exceed recommended dosage.
DOES NOT CONTAIN: Gluten, Soy, Binders
CAUTION: For adults only. Consult your healthcare provider if you are pregnant, nursing, have a medical condition, or are taking other nutritional supplements or medications. Keep away from
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.
FSC
Please recycle
Life looks different lately—your hair might, too. For new moms experiencing thinning or over-shedding, we see you. The journey towards a body and hair in balance starts here, at the root of it—with a natural, breastfeeding-friendly wellness routine that targets physical and emotional stressors, hormonal changes, and nutrient depletion from within.*
LEARN MORE AT NUTRAFOL.COM


NUTRAFOL
POSTPARTUM
HAIR GROWTH NUTRACEUTICAL*
DIETARY SUPPLEMENT
120 CAPSULES
Supplement Facts
Hair Wellness from Within®.
OBGYN-developed to multi-target key root causes of postpartum thinning hair. These natural ingredients support whole-body recovery after childbirth while filling nutritional gaps for healthier hair growth. With breastfeeding-friendly Synergen Recovery Complex.*
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

36. Even assuming that Defendant's DSHEA Disclaimers comply with the FDA, they do not, most consumers. like Plaintiff, who purchased the Products online would only have been able to see them after paying for them and receiving them in the mail. Specifically, Defendant fails to include the DSHEA Disclaimer on its Amazon.com[27] listings in visual proximity to the multiple statements that it makes about the Products. Instead, the DSHEA Disclaimers are buried at the very bottom of the webpages under the subheadings "Safety Information"—which includes unrelated information; is not set apart from the block of text as required under the FDA regulations; and does not contain a conspicuous asterisk which links it to the myriad of asterisks, numbers, and symbols littered throughout the webpages. *See* Exhibit A. Finally, the DSHEA Disclaimers are easy to miss because most consumers click the "Add to Cart" or "Buy Now" buttons before scrolling the approximately 7 pages on each listing before reaching these inadequate disclaimers.

Defendant's Products are Adulterated and Illegal to Sell under the FDCA and Worthless

37. Because Defendant intended to sell the Products as drugs, or, alternatively, made improper "disease" claims and failed to include adequate Defendant's DSHEA Disclaimers within the Products' labeling and marketing, the Products constitute "new drugs" under the FDCA. 21 U.S.C. § 321(p). A new drug may not be introduced into interstate commerce unless it is approved by the FDA through a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(a). Defendant's Products were not approved by the FDA under an NDA or ANDA. Furthermore, Defendant's Products are "misbranded "under the FDCA because they are intended for the treatment of one or more diseases that are not amenable

[27] Upon information and belief, Defendant only sells its Products through its own website and on Amazon.com

to self-diagnosis or treatment without the supervision of a licensed practitioner. As such, it is impossible to write adequate directions for the Products' intended purposes as required under the FDCA. 21 U.S.C. 352(f)(1).

38. Based on the foregoing, Defendant's Products are illegal to sell because they are both adulterated and unapproved new drugs, which are to sell under the FDCA. 21 U.S.C. §§ 331(a), (d). Such illegally sold Products are worthless and have no value. *See Debernadis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019).

Defendant's Products Are Not "Clinically Proven" or "Backed by Science"

39. Throughout its Advertising, Defendant claims that its Products' have been "clinically proven" and "backed by science." These statements, however, are false and misleading. Under FTC guidance to advertisers of dietary supplements, claims about the efficacy of dietary supplements must be supported by "competent and reliable scientific evidence," which the FTC defines as "**tests, analyses, research, studies or other evidence, based on the expertise of professionals in the relevant area**, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[28]

40. As discussed in greater detail throughout Truth in Advertising's letter to the FTC, all of the studies conducted by Defendant are flawed on multiple grounds. Exhibit B at pgs. 5-10. Most alarmingly, the test results findings about the percentage of hair growth from using the Products—which Defendant prominently advertises—are based on the participant's subjective self-assessments at the end of the study rather than "objective measurements by blinded

[28] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-substantiation-dietary-supplement-claims-made-under-section-403r-6-federal-food#ftn7

investigators." *Id.* at pg. 6.[29] In fact, the only objective measurements performed in the studies "did not find any significant changes in mean hair diameter, which was measured using microscopic digital images." *Id.*

41. Despite all this, Defendant knowingly continues to sell the Products to consumers with unsupported claims that the Products are "clinically proven" and "backed by science" despite the falsity of those statements.

42. Defendant's misleading representations and illicit sale of the Products proximately caused harm to Plaintiff and the proposed class members who suffered an injury in fact and lost money or property as a result of Defendant's conduct.

CLASS ACTION ALLEGATIONS

43. Plaintiff brings this action on behalf of herself and all other similarly situated persons pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), and (b)(3). Specifically, the Classes are defined as:

> **Nationwide Class:** All persons in the United States who, during the maximum period of time permitted by law, purchased Defendant's Products primarily for personal, family or household purposes, and not for resale.
>
> **New York Subclass:** All persons residing in New York who, during the maximum period of time permitted by the law, purchased Defendant's Products primarily for personal, family or household purposes, and not for resale.

44. The Classes do not include (1) Defendant, their officers, and/or its directors; or (2)

[29] Citing Glynis Ablon MD FAAD and Sophia Kogan MD, *A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair*, 17(5) J. Drugs Dermatol. at 562.

the Judge to whom this case is assigned and the Judge's staff.

45. Plaintiff reserves the right to amend the above class definitions and add additional classes and subclasses as appropriate based on investigation, discovery, and the specific theories of liability.

46. ***Community of Interest***: There is a well-defined community of interest among members of the Classes, and the disposition of the claims of these members of the Classes in a single action will provide substantial benefits to all parties and to the Court.

47. ***Numerosity***: While the exact number of members of the Classes is unknown to Plaintiff at this time and can only be determined by appropriate discovery, upon information and belief, members of the Classes number in the millions. The precise number of the members of the Classes and their identities are unknown to Plaintiff at this time but may be determined through discovery. Members of the Classes may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

48. ***Existence and predominance of common questions of law and fact***: Common questions of law and fact exist as to all members of the Classes and predominate over any questions affecting only individuals of the Classes. These common legal and factual questions include, but are not limited to:

(a) Whether the Products are illegal to sell in violation of the FDCA;

(b) Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products make diseases claims in violation of the FDCA;

(c) Whether Defendant fraudulently induced Plaintiff and the members of the Classes into purchasing the Products by claiming that the Products were "clinically proven" and "backed by science";

(d) Whether Plaintiff and the members of the Classes have suffered damages as a result of Defendant's actions and the amount thereof;

(e) Whether Plaintiff and the members of the Classes are entitled to statutory damages;

(f) Whether Plaintiff and the members of the Classes are entitled to attorney's fees and costs.

49. ***Typicality:*** The claims of the named Plaintiff are typical of the claims of other members of the Classes in that the named Plaintiff was exposed to Defendant's false and misleading marketing, purchased Defendant's illegal Products, and suffered a loss as a result of those purchases.

50. ***Adequacy***: Plaintiff will fairly and adequately represent and protect the interests of the Classes as required by Federal Rule of Civil Procedure Rule 23(a)(4). Plaintiff is an adequate representative of the Classes because she has no interests which are adverse to the interests of the members of the Classes. Plaintiff is committed to the vigorous prosecution of this action and, to that end, Plaintiff has retained skilled and experienced counsel.

51. Moreover, the proposed Classes can be maintained because they satisfy both Rule 23(a) and 23(b)(3) because questions of law or fact common to the Classes predominate over any questions affecting only individual members and that a Class Action is superior to all other available methods of the fair and efficient adjudication of the claims asserted in this action under Federal Rule of Civil Procedure 23(b)(3) because:

(a) The expense and burden of individual litigation makes it economically unfeasible for members of the Classes to seek to redress their claims other than through the procedure of a class action;

(b) If separate actions were brought by individual members of the Classes, the resulting duplicity of lawsuits would cause members of the Classes to seek to redress their claims other than through the procedure of a class action; and

(c) Absent a class action, Defendant likely will retain the benefits of their wrongdoing, and there would be a failure of justice.

CAUSES OF ACTION

COUNT I
Violation of State Consumer Protection Statues[30]
(On Behalf of Plaintiff and the Nationwide Class)

52. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

53. The Consumer Protection Statutes of the Nationwide Class members prohibit the

[30] While discovery may alter the following, Plaintiff asserts that the states with similar consumer fraud laws under the facts of this case include but are not limited to: Alaska Stat. § 45.50.471, et seq.; Ariz. Rev. Stat. §§ 44-1521, et seq.; Ark. Code § 4-88-101, et seq.; Cal. Bus. & Prof. Code § 17200, et seq.; Cal. Civ. Code §1750, et seq.; Colo. Rev. Stat. Ann. § 6-1-101, et seq.; Colo. Rev. Stat. Ann. § 6-1-101, et seq.; Conn. Gen Stat. Ann. § 42- 110, et seq.; 6 Del. Code § 2513, et seq.; D.C. Code § 28-3901, et seq.; Fla. Stat. Ann.§ 501.201, et seq.; Ga. Code Ann. § 10-1-390, et seq.; Haw. Rev. Stat. § 480-2, et seq.; Idaho Code. Ann. § 48-601, et seq.; 815 ILCS 501/1, et seq.; Ind. Code § 24-5-0.5-2, et seq.; Kan. Stat. Ann. § 50-623, et seq.; Ky. Rev. Stat. Ann. § 367.110, et seq.; LSA-R.S. 51:1401, et seq.; Me. Rev. Stat. Ann. Tit. 5, § 207, et seq.; Md. Code Ann. Com. Law, § 13-301, et seq.; Mass. Gen Laws Ann. Ch. 93A, et seq.; Mich. Comp. Laws Ann. § 445.901, et seq.; Minn. Stat. § 325F, et seq.; Mo. Rev. Stat. § 407, et seq.; Neb. Rev. St. §§ 59-1601, et seq.; Nev. Rev. Stat. § 41.600, et seq.; N.H. Rev. Stat. § 358-A:1, et seq.; N.J. Stat. Ann. § 56:8, et seq.; N.M. Stat. Ann. § 57-12-1, et seq.; N.Y. Gen. Bus. Law § 349, et seq.; N.C. Gen Stat. § 75-1.1, et seq.; N.D. Cent. Code § 51-15, et seq.; Ohio Rev. Code Ann. § 1345.01, et seq.; Okla. Stat. tit. 15 § 751, et seq.; Or. Rev. Stat. § 646.605, et seq.; 73 P.S. § 201-1, et seq.; R.I. Gen. Laws § 6-13.1- 5.2(B), et seq.; S.C. Code Ann. §§ 39-5- 10, et seq.; S.D. Codified Laws § 37-24-1, et seq.; Tenn. Code Ann. § 47-18-101, et seq.; Tex. Code Ann., Bus. & Con. § 17.41, et seq.; Utah Code. Ann. § 13-11-175, et seq.; 9 V.S.A. § 2451, et seq.; Va. Code Ann. § 59.1-199, et seq.; Wash. Rev. Code § 19.86.010, et seq.; W. Va. Code § 46A, et seq.; Wis. Stat. § 100.18, et seq.; and Wyo. Stat. Ann. § 40-12-101, et seq.

use of deceptive, unfair, and misleading business practices in the conduct of trade or commerce.

54. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by conspicuously representing on the marketing of the Products that they are "clinically proven" to improve "hair growth" and prevent "shedding." Despite those representations, however, the Products are not backed by reliable scientific evidence. Furthermore, the Products are misbranded and unapproved "new drugs" which are illegal to sell under the FDCA.

55. The foregoing deceptive acts and practices were directed at consumers.

56. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the nature and value of the Products.

57. As a result of Defendant's deceptive practices, Plaintiff and the Nationwide Class members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known that the Products were not, indeed, "clinically proven" to improve "hair growth" and prevent "shedding" and otherwise unapproved new drugs which are misbranded and illegal to sell.

58. On behalf of herself and the Nationwide Class members, Plaintiff seeks to recover their actual damages, statutory damages, punitive damages, and reasonable attorneys' fees and costs.

COUNT II
Violation of New York G.B.L. § 349
(On Behalf of Plaintiff and the New York Subclass)

59. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

60. New York's General Business Law § 349 prohibits deceptive acts or practices in

the conduct of any business, trade, or commerce.

61. In its sale of Products throughout the state of New York, at all relevant times herein, Defendant conducted business and trade within the meaning and intendment of New York's General Business Law § 349.

62. Plaintiff and the New York Subclass members are consumers who purchased the Products from Defendant for their personal use.

63. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by conspicuously representing on the marketing of the Products that they are "clinically proven" to improve "hair growth" and prevent "shedding." Despite those representations, however, the Products are not backed by reliable scientific evidence. Furthermore, the Products are misbranded and unapproved "new drugs" which are illegal to sell under the FDCA.

64. The foregoing deceptive acts and practices were directed at consumers.

65. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the nature and value of the Products.

66. As a result of Defendant's deceptive practices, Plaintiff and the Nationwide Class members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known that the Products were not, indeed, "clinically proven" to improve "hair growth" and prevent "shedding" and otherwise unapproved new drugs which are misbranded and illegal to sell.

67. On behalf of herself and the New York Subclass members, Plaintiff seeks to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees and costs.

COUNT III
Violation of New York G.B.L. §350
(On Behalf of Plaintiff and the New York Subclass)

68. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

69. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

70. Defendant violated New York General Business Law § 350 by misrepresenting that the Products as "clinically proven" to improve "hair growth" and prevent "shedding." Despite those representations, however, the Products are not backed by reliable scientific evidence. Furthermore, the Products are unapproved "new drugs" which are misbranded and illegal to sell under the FDCA.

71. The foregoing advertising was directed at consumers and was likely to mislead a reasonable consumer acting reasonably under the circumstances.

72. Defendant's misrepresentations have resulted in consumer injury or harm to the public interest.

73. As a result of Defendant's deceptive practices, Plaintiff and the Nationwide Class members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known that the Products were not, indeed, "clinically proven" to improve "hair growth" and prevent "shedding" and otherwise unapproved new drugs which are misbranded and illegal to sell.

74. On behalf of herself and the New York Subclass members, Plaintiff seeks to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendant, as follows:

(a) For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure; naming Plaintiff as representative of the Classes; and naming Plaintiff's attorneys as Class Counsel to represent the Classes;

(b) For an order finding in favor of Plaintiff and the Classes on all counts asserted herein;

(c) For compensatory, statutory and punitive damages in amounts to be determined by the Court and/or jury;

(d) For prejudgment interest on all amounts awarded;

(e) For an order of restitution and all other forms of equitable monetary relief; and

(f) For an order awarding Plaintiff and the Classes their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable as of right.

Dated May 4, 2023

Respectfully submitted,

GUCOVSCHI ROZENSHTEYN, PLLC

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